

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 15 MAY 2006

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Applicant's or agent's file reference 000711-0058	FOR FURTHER ACTION <div style="text-align: right;">See Form PCT/IPEA/416</div>																	
International application No. PCT/CA2005/000138	International filing date (<i>day/month/year</i>) 03 February 2005 (03-02-2005)	Priority date (<i>day/month/year</i>) 03 February 2004 (03-02-2004)																
International Patent Classification (IPC) or national classification and IPC IPC: A23K 1/16 (2006.01) , A23K 1/18 (2006.01)																		
Applicant UNIVERSITE DE MONTREAL ET AL																		
<ol style="list-style-type: none"> 1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet. 3. This report is also accompanied by ANNEXES, comprising: <ol style="list-style-type: none"> a. <input checked="" type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of <u>2</u> sheets, as follows: <div style="margin-left: 20px;"> <input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. 1 and the Supplemental Box. </div> b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) <div style="margin-left: 20px;"> , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions). </div> 4. This report contains indications relating to the following items: <table style="width: 100%; border: none;"> <tr> <td style="width: 10%;"><input checked="" type="checkbox"/> Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/> Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/> Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/> Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/> Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/> Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/> Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table> 			<input checked="" type="checkbox"/> Box No. I	Basis of the report	<input type="checkbox"/> Box No. II	Priority	<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/> Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/> Box No. VI	Certain documents cited	<input type="checkbox"/> Box No. VII	Certain defects in the international application	<input type="checkbox"/> Box No. VIII	Certain observations on the international application
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Date of submission of the demand 02 December 2005 (02-12-2005)	Date of completion of this report 10 May 2006 (10-05-2006)																	
Name and mailing address of the IPEA/CA Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001(819)953-2476	Authorized officer Elizabeth A. McKay Andrews (819) 997-2950																	

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/CA2005/000138

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rules 12.3(a) and 23.1(b))
- ☐ publication of the international application (Rule 12.4(a))
- ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

- ☐ the international application as originally filed/furnished
- ☒ the description:
- | | | | |
|--|-------------|-------------------------------|--------------------------------------|
| <input checked="" type="checkbox"/> pages | <u>2-31</u> | | as originally filed/furnished |
| <input checked="" type="checkbox"/> pages* | <u>1,1a</u> | received by this Authority on | <u>02-12-2005 (02 December 2005)</u> |
| <input type="checkbox"/> pages* | | received by this Authority on | |
- ☒ the claims:
- | | | | |
|---|--------------|---|-------------------------------|
| <input checked="" type="checkbox"/> pages | <u>32-34</u> | | as originally filed/furnished |
| <input type="checkbox"/> pages* | | as amended (together with any statement) under Article 19 | |
| <input type="checkbox"/> pages* | | received by this Authority on | |
| <input type="checkbox"/> pages* | | received by this Authority on | |
- ☒ the drawings:
- | | | | |
|---|----------------|-------------------------------|-------------------------------|
| <input checked="" type="checkbox"/> pages | <u>1/3-3/3</u> | | as originally filed/furnished |
| <input type="checkbox"/> pages* | | received by this Authority on | |
| <input type="checkbox"/> pages* | | received by this Authority on | |
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/CA2005/000138**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	<u>1-30</u>	YES
	Claims	<u>none</u>	NO
Inventive step (IS)	Claims	<u>1-30</u>	YES
	Claims	<u>none</u>	NO
Industrial applicability (IA)	Claims	<u>1-30</u>	YES
	Claims	<u>none</u>	NO

2. Citations and explanations (Rule 70.7)

1 Reference is made to the following documents:

D1 US 6500423
D2 WO 99/08532

- 2 D1 represents the closest prior art and teaches non-pathogenic probiotic microorganisms derived from *E. coli* are capable of restoring normal GI flora of man and a variety of mammals and avians. The use of *Escherichia coli* strain BU-230-98 ATTC Deposit No. 20226 (column 3, lines 49-51) fed with a vegetal volatile fraction, is shown to decrease mortality and improve weight gain for piglets (Example 14), effectively treat lambs and goat kids for pathogenic *E. coli* infections (Example 19), to improve weight gain and treat diarrhea in poultry (Example 20), and treat symptoms of diarrhea in puppies (Example 21).

D2 teaches specific strains of probiotic *E. coli* having the property of inhibiting the growth of pathogenic *E. coli* O157:H7 in ruminants.

- 3 The F4-positive non-pathogenic *E. coli* strain used in the present invention is distinguished from that taught in D1 or those taught in D2. Further, the present invention demonstrates the F4-positive *Escherichia coli* strain defined in the claims is shown to promote growth in healthy animals, independently of a potential effect on prevention or treatment of diseases affecting negatively the weight gain, such as enteritis.

Claims 1-30 meet the requirements of novelty and inventive stop and satisfy Article 33(2) and (3) PCT.

- 4 Claims 1-30 meet the requirements of Article 33(4) because optimizing weight gain in meat animals is of industrial applicability.

USE OF LIVE BACTERIA FOR GROWTH PROMOTION IN ANIMALS

FIELD OF THE INVENTION

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The present invention relates to the field of growth promotion in animals. More specifically, the present invention relates to the use of a non-pathogenic *Escherichia coli* strain expressing the F4 (or K88) attachment factor, to either promote growth in animals or homogenize growth among a herd of animals.

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BACKGROUND OF THE INVENTION

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Growth promotion is a crucial issue for farm and breeding specialists, who mainly seek to optimize the production of healthy animals before slaughter or for research purposes. Such a concern should lead them to use growth promoting products that would prove beneficial to the animals and also to humans, in the case of meat-producing animals.

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It has been disclosed in the art, namely, in US patent no. 6 500 423, that the use of a formulation containing a F4-negative *E. coli* strain of human origin and a vegetal volatile fraction allegedly improve weight gain in piglets. The growth promotion observed was associated with the vegetal volatile fraction and not the F4-negative *E. coli* strain.

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One major caveat in farms and breeding environments is the weight loss, slow growth rate along with a recrudescence of concomitant diseases, drug cost, and mortality which lead to a decrease in animal yields and ultimately to considerable economic losses. In this connection, post-weaning or post-hatching animals are particularly vulnerable to agents impeding growth.

Infections caused by either non-hygienic conditions or close proximity between animals, for example, are among the most common factors leading to the above-mentioned caveat.

02 DECEMBER 2005 02.12.05

One conventional solution used to alleviate this problem has been to use antibiotic growth promoters in feeds. However, use of antibiotic growth promoters is also highly controversial because, as is well known, even at sub-therapeutic doses, continued antibiotic use can lead to selection of antibiotic-resistant bacterial strains in the treated animals (Arnold S *et al.*; Wegener HC *et*
